Significant Analysis
for Rules Concerning Immunization Requirements
Related to Schools and Child Care Centers

Chapter 246-105 WAC, creating a new chapter; repealing WAC 246-100-166

Briefly describe the proposed rule.

WAC 246-100-166 concerns immunization requirements for children attending licensed child care centers, preschools and all K-12 schools in Washington State. In general, the current WAC establishes which vaccines are required for students at which grade (or age for preschool children in child care), the federal immunization guidelines to be followed, and the recordkeeping requirements parents, schools, preschools, and child care centers must follow.

The proposed rule intends to accomplish the following:

1. Add pneumococcal to the list of vaccine-preventable diseases that children are required to be vaccinated against before attending child care or preschool. The effective date of July 1, 2009 is written into the rule. Because the vaccine for this disease is licensed for children less than 5 years of age, this will not apply to grades kindergarten or higher.

2. Update the reference to the Advisory Committee on Immunization Practices' (ACIP) Recommended Childhood and Adolescent Immunization Schedule from the 2007 version to the 2008 version. The ACIP, a federal body working with the Centers for Disease Control and Prevention, sets childhood and adolescent immunization guidelines at the beginning of each calendar year. As the rule references this schedule, it must also be updated annually to reflect the most current standards. As with the pneumococcal requirement, this part of the rule will be effective July 1, 2009.

3. Re-codify WAC 246-100-166 into nine sections within new chapter 246-105 WAC. This is to improve clarity and administrative efficiency. By separating parts of the rule, it will be possible to update to the annual ACIP schedule through a faster, simpler and less costly "exception rule" process. A standard rule process for significant policy changes (such as adding requirements for another vaccine-preventable disease) may be done simultaneously, if needed.

4. Better define terms used throughout the current WAC 246-100-166. As text is reorganized, the SBOH is taking the opportunity to provide more clarity to several definitions and federal referencing guidelines.

Is a Significant Analysis required for this rule?

Portions of this rule require a significant analysis. However, Washington State Department of Health (DOH) and State Board of Health (SBOH) have determined that no significant analysis is required for numbers two, three and four of the rule as detailed above. Given the 2008 ACIP schedule has no substantive changes from the 2007 version; this will be only a technical update. Re-codification is also for technical reasons and not intended as a policy re-write of existing language. Edits to terms, conditions, and federal references are for clarification purposes and do not entail significant changes to the existing rule. Because these aspects of the proposal do not significantly amend a policy or regulatory program, significant analysis is not needed.

The remainder of this document will focus on those portions of the rule that require a significant analysis; specifically, adding pneumococcal to the list of vaccine-preventable diseases children are required to be vaccinated against before attending child care or preschool.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The rule implements RCW 28A.210.060 through RCW 28A.210.170. Their statutory purpose is to protect the public's health by preventing vaccine-preventable disease outbreaks in schools and child care centers. This is done through immunization requirements for certain diseases before allowing children into these settings. Parents must provide the proper immunization documentation which schools and child care centers must keep on file. The SBOH is given the authority to examine and decide which diseases are required for vaccination and how they are to be documented.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

The SBOH established a Technical Advisory Group (TAG) to provide recommendations on whether immunization against pneumococcal disease should be required for child care center and preschool entry. The purpose was to examine the antigen's burden of disease, the effectiveness of the vaccine, and its implementation by applying nine criteria developed by the SBOH. After meeting in July of 2007, the TAG determined that requiring vaccination for this disease was reasonable and in the interest of our public health, thus achieving the goals of the underlying statutes. The SBOH accepted their recommendation that a child care center and preschool requirement for pneumococcal vaccination be added to the rule.

Individual states determine immunization requirements for schools and child care centers. There is no alternative available other than rule-making to require pneumococcal vaccination for these groups.

Consequences of not adopting the rule would be a lower percentage of children protected from pneumococcal disease and a higher risk of infection. Pneumococcal infections cause severe disease and even death in children less than five years of age. Types of disease include meningitis (infection of the covering of the brain), several kinds of blood infection, and ear infection. Currently, about 76 percent of children 19 to 35 months of age in Washington receive the full four-dose series recommended for the pneumococcal vaccine (called seven-valent pneumococcal conjugate vaccine, or PCV7). With the addition of a child care center and preschool requirement, the DOH estimates this vaccination rate to reach 95 percent by 2011.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits, and costs and the specific directives of the statute being implemented.

Background: Streptococcus Pneumonia causes several invasive diseases such as pneumonia, meningitis, and bacteremia in children. These diseases are often very serious and can be life threatening.

Wyeth Vaccines developed and manufactures a seven-valent pneumococcal conjugate vaccine (PCV7), marketed as Prevnar, principally to address Invasive Pneumoccal Disease among infants.

The United States Government's Food and Drug Administration approved PCV7 for use in infants in 2000. After it was approved, the ACIP made an initial recommendation of the vaccine for all children less than two years old and a modified recommendation (i.e., less than 100 percent coverage recommendation) for high risk children between two years and six years old due to (1) a shortage of supply of the vaccine at that time, and (2) a question if the costs of the vaccine outweighed the benefits for children in this age category. Routine infant immunization began shortly after.

In October 2007 with an end to the shortage and also increased experience with this vaccine, the ACIP revised and updated its recommendation of the use of PCV7 in the following manner:

PCV7 is continued to be recommended for routine administration as a four dose series for infants at ages 2, 4, 6, and 12 to 15 months. Catch-up immunization is recommended for children aged less than 23 months, using fewer doses depending on age at the time of first vaccination.

Furthermore, the ACIP made the following recommendations for children older than 23 months:

All healthy children aged 24-59 months, who have not completed any recommended schedule for PCV7, receive one dose of PCV7.

All children aged 24-59 months with underlying medical conditions who have received three doses receive one additional dose of PCV7.

All children aged 24-59 months with underlying medical conditions who have received less than three doses receive two doses of PCV7 at least eight weeks apart.

Effectiveness of Vaccine: Since its introduction, several researchers have studied the effectiveness of the PCV7 in reducing invasive pneumococcal diseases[1]. The PCV7 vaccine has shown to be highly effective. Grijalva's study looked at data from the National Inpatient Sample, the largest inpatient database available in the USA, and analyzed the data with an interrupted time-series analysis that used pneumonial (all-cause and pneumococcal) admission rates as the main outcomes.

Grijalva compared the monthly admission rates for four years before and four years after the introduction of PCV7, which showed all-cause pneumonia admission rates had declined by 39 percent (95 percent confidence interval (CI) 22-52) for children younger than 2 years. This correlated to an annual decline in all-cause pneumonia admissions of 506 (291-675) per 100,000 children younger than two years, which represented about 41,000 pneumonia admissions prevented in 2004. Furthermore, during the eight year study, 10,659 (2 percent) children younger than 2 years admitted with pneumonia were coded as having pneumoncoccal disease. These rates declined by 65 percent. This decline represented about 17 fewer admissions per 100,000 children in 2004.

Grijalva also conducted another study that looked at how the rate of outpatient medical care visits changed in the United States before (data from 1994-1999) and after PCV7 was introduced (data from 2002-2003). This study specifically looked at visits associated with otitis media events. He found that the national rate of otitis media visits declined by approximately 20 percent, which is a significant reduction, in children less than 2 years old (246 fewer otitis media visits per 1000 children).

In another study Poehling, et al[2] looked at how the rate of otitis media and pressure equalizing tube insertions changed in children after introduction of PVC7. This study examined data from children from New York and Tennessee and spanned from 1998 to 2002. When comparing data from 1998-1999 (children with less than 1 percent uptake) and 2000-2001 (children with approximately 75 percent uptake), the study found that frequent otitis media declined by 17 percent and 28 percent and pressure-equalizing tube insertions declined by 16 percent and 23 percent for Tennessee and New York Children, respectively.

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[1] Decline in pneumonia admissions after routine childhood immunization with pneumococcal conjugate vaccine in the USA: a time-series analysis; Carlos G. Grijalva, et al, "The Lancet", vol 369, April 7, 2007 pages 1179-1186

[2] Reduction of Frequent Otitis Media and Pressure-Equalizing Tube Insertions in Children After Introduction of Pneumococcal Conjugate Vaccine; Katherine A Poehling, et al, "Pediatrics", Volume 119 Number 4, April 2007.

Invasive pneumococcal disease is generally spread from individuals that carry the disease in their nasal passages and thus, people that are vaccinated do not infect others when they sneeze or cough. Young children receive the vaccine benefit through reduced disease incidence as noted above. In addition, their immunity keeps them from spreading diseases to others, protecting the general public by reducing the amount of circulating disease and creating herd immunity. Thus, vaccinating young children reduces disease rates and the health care costs associated with these diseases for older children, adults, and the elderly.

Costs: Ray, et al, conducted a study that looked at protections provided to vaccinated children. He also estimated the value of the vaccine to the rest of the US population, which were unvaccinated (commonly referred to as the herd effect). Ray's study identified the cost effectiveness of PCV7 since it was first administered in 2000 and assessed the benefits of prevented diseases (morbidity) and also estimated the number of lives saved due to the vaccine's use. Ray completed this study at the request of the CDC. He updated the model that was developed for the original cost-effectiveness study, which looked at a single cohort prior to the administration of the vaccine. Ray's model incorporated revised vaccine efficacy data and includes nationally representative costs and incidence data.

Ray's study assessed the cost of the vaccine and identified direct medical cost savings, out-of-pocket costs and work loss savings, and identified the estimated number of lives saved by the vaccine's use. His study, however, did not include an estimated value of life saved. The value of a statistical life ranges from $1 to $16 million in economic impact studies. The values are based on cost of illness, wage and risk studies, and reported willingness to pay. The values typically cluster in the $3 million to $7 million range. For this analysis we used $4 million dollars as the value of life, which has been referenced and used previously in Department of Health cost effectiveness/benefit analyses. We have incorporated the value of life saved into the other benefits that Ray's study identified. The table on the following page was developed from information in several tables in the Ray study[3] along with the estimated value of lives saved. When assigning a value to a life saved into the analysis, the results showed that the benefits of the vaccine outweigh its costs.

[3] Cost-Effectiveness of Pneumococcal Conjugate Vaccine- Evidence from the First 5 years of Use in the United States Incorporating Herd Effects, Ray et al, "The Pediatric Infectious Disease Journal, Volume 25, Number 6, June 2006 Pages 494-501.

Estimated Pneumococcal Disease Episodes Prevented, Costs and Benefits in the First 5 years after Introduction of PCV7 (2000-2004)

Variable	Vaccinated Children	Unvaccinated Children Under 5 Yrs (Herd Effect)	Unvaccinated Children and Adults 5 <65 Years (Herd Effect)	Nonvaccinated Adults (Herd Effect)	All Persons
Estimated number of children vaccinated	13,800,000				13,800,000
Estimated number of vaccinations	51,600,000				51,600,000
Otitis episodes prevented	2,600,000				2,600,000
Pneumonia (inpatient and outpatient) prevented	154,000				154,000
Invasive disease prevented	38,000	15,600	33,100	22,600	109,300
Direct Medical Costs Savings	902,000,000	82,000,000	343,000,000	214,000,000	1,541,000,000
Out of pocket and work-loss savings	780,000,000	20,000,000			800,000,000
Total Deaths Prevented	421	163	1885	2690	5159
Value of Life Saved (Deaths Prevented @ (4,000,000) per life[4]	1,684,000,000	652,000,000	7,540,000,000	10,760,000,000	20,636,000,000
Total Benefits	3,366,000,000	754,000,000	7,883,000,000	10,974,000,000	$22,977,000,000
Total Cost of Vaccination Program @ $61 per dose	$(2,900,000,000)				$(2,940,000,000)
Excess Benefits of Vaccination Program					$20,037,000,000

Status of PCV7 use in Washington State: The Office of Financial Management (OFM) projects that there are approximately 87,000 births in Washington each year. Washington implemented pneumococcal vaccination in 2000. During the time since it was implemented, vaccine coverage rates have gradually increased. Based on information collected from a survey of Washington State residents through the 2006 National Immunization Survey 89 percent of children received three doses of PCV7 and 76

[4] Richard Layard and Stephen Glaister, Cambridge University Press, 1994 W. Kip Viscusi "The Value of Risks to Life and Health" J. of Econ. Lit. Vol 31 Dec. 1993 W. Kip Viscusi: Journal of Risk and Uncertainty Vol 8 No 1 1994 reprinted by Kluwer Academic Publishers which has a large set of articles with arguments on values from both sides.

percent received four doses. This rule requires all children to be age appropriately vaccinated against pneumococcal disease. Age appropriate vaccination includes one dose of vaccine for infants at ages 2, 4, 6, and 12 to 15 months, for a complete series of 4 doses. If a child has not received the full four dose series by age 15 months, the rule requires them to receive age appropriate "catch-up" vaccinations, based on the recommendations of the ACIP schedule. The number of doses of vaccine the child needs to catch-up depends upon their age, and the number of doses they have already received. The vaccine is not administered to children five years of age or older.

Summary of Benefits and Costs of Requiring Vaccine in Washington State: Our assumption is that by age 5, 95 percent[5] of all newborn children will be administered a four doses regiment of PCV7, which equates to 82,650 children (95 percent of 87,000) each subsequent year. Each dose of PCV7 costs $78.44 in the private sector. Washington is able to leverage the use of the Centers for Disease Control and Prevention's vaccine contract to purchase the vaccine at $66.44 for Washington's Universal Childhood Vaccine Program. This creates a savings of about 15 percent below the private sector cost, and results in savings of approximately $1.5 million for just the state portion of the cost of purchasing the vaccine. The resulting total annual cost of a four shot PCV7 regiment is approximately $23,121,120 assuming 100 percent vaccination coverage. Washington uses a combination of state and local funds to purchase childhood vaccines, and approximately $8.5 million of the projected $23,121,120, would be state funding.

Child care and pre-school organizations currently inform parents about immunization requirements and check immunization status as a routine part of their business practice. Vaccination status for all vaccines is captured on a single form (the Certificate of Immunization Status) provided by the Washington State Department of Health. The rule requires child care centers and pre-school organizations add this vaccine to their current information. One additional vaccine will be captured on the CIS and be reviewed by child care and pre-school organizations. Since these activities are part of their routine business practices, they are expected to result in negligible cost to these organizations. Expenses related to the informational and review activities of these organizations are therefore not included in these analyses.

Assuming Washington State receives its representative share of the total national benefit of the vaccine program (e.g., 2 percent of approximate $23,000,000,000 for a repeating five year vaccine cycle), the benefits of this program exceed the costs to administer and implement the vaccine in Washington State.

Note: the Ray study used a mean dose cost of $52, with a administrative cost of $9.15 per dose. Although the cost of the vaccine has risen (federal contract price is now $66.44),

[5] DOH based the 95% level on the likelihood that some parents will not elect to have their children administered vaccines due to religious beliefs or other reservations about the use of vaccines.

using the higher dose cost will not change the end result that the overall benefits still far exceed the cost of this program. .

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

An effective date as soon as January 1, 2009 (meaning 31 days after filing the final order for the rule) was considered for implementing the pneumococcal requirement. The primary reason was that more children could be protected sooner. Normally, effective dates for new vaccine policies added to this rule are delayed several months to the first day of July immediately following a proposal's adoption. This delay is used to ensure adequate communication about the rule change to parents, providers, child care, preschools and schools. It also allows infrastructure preparation within child cares, preschools and schools.

For this and past proposals to this rule, DOH and SBOH have worked closely with parents, child care center and preschool professionals, and state agencies such as the Department of Early Learning and Office of the Superintendent of Public Instruction to determine the best means and timing of implementation. When compared to the alternative effective date for the pneumococcal requirement (31 days post filing), the proposed rule's delayed effective date of July 1, 2009 is more practical and less burdensome for child care centers and preschools. It allows sufficient time for these facilities adjust their recordkeeping and provide the necessary parental notification and education. Without this preparation, the inability to comply with this requirement is significantly increased.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

Not applicable.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

All child care center and preschool immunization requirements in this rule, including those proposed for pneumococcal, apply consistently to public and private entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not deviate from any applicable federal regulation, statute or guideline.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no major policy matters needing coordination with any other state or local laws because of this rule proposal. However, the Department of Early Learning, the State Board of Education and the Office of the Superintendent of Public Instruction each would need to adjust references in certain WAC under their authority due to this rule's re-codification. All three agencies have had opportunity to review and comment on the rule proposal. If the rule passes, the department would again notify them of any necessary "housekeeping" issues.

Federal immunization guidelines are established by the ACIP. Following these guidelines is a condition for states to receive federal funding through the Social Security Act's Vaccines for Children program. This rule remains consistent with these federal guidelines by establishing ACIP recommendations as the standard for not only pneumococcal vaccination, but every vaccination required for school or child care entry. It also updates the reference of the ACIP immunization schedule from the 2007 version to the 2008 version to reflect the most current guidelines.